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MAR 7 - 2007
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SUPREME COURT, U.S.

No. 06-1016

In The
Supreme Court of the United States

RANBAXY LABORATORIES LIMITED AND
RANBAXY PHARMACEUTICALS INC.,

Petitioners,

—against—

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS,
WARNER-LAMBERT COMPANY,
WARNER-LAMBERT COMPANY, LLC, AND
WARNER-LAMBERT EXPORT, LTD.,

Respondents.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit**

REPLY BRIEF

WILLIAM R. ZIMMERMAN
Counsel of Record
DARRELL L. OLSON
JOSEPH M. REISMAN
PAYSON LEMEILLEUR
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, California 92614
(949) 760-0404

Attorneys for Petitioners

March 7, 2007

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OR CALL COLLECT (402) 342-2831

CORPORATE DISCLOSURE STATEMENT

No publicly held company owns 10% or more of the stock of Petitioner Ranbaxy Laboratories Limited. Petitioner Ranbaxy Pharmaceuticals Inc. is a wholly-owned subsidiary of Ranbaxy [Holdings] UK Ltd., which is a wholly-owned subsidiary of Ranbaxy Netherlands B.V., which is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

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REPLY BRIEF ON PETITION FOR WRIT OF CERTIORARI

Pursuant to United States Supreme Court Rule 15, Ranbaxy hereby submits this Reply Brief in support of the Petition for Writ of Certiorari.

I. THE QUESTION PRESENTED FOR REVIEW IS ONE OF LAW, NOT FACT

Throughout its Brief in Opposition to the Petition for Writ of Certiorari, Pfizer characterizes the Federal Circuit's patent term extension ruling as "a clear error affirmance of a district court factual finding." *See, e.g.,* Brief in Opposition filed February 26, 2007 at 8.[1] However, Pfizer's repeated mischaracterizations cannot alter the District Court's and Federal Circuit's opinions and analyses. In assessing materiality, neither Court considered the substance of Pfizer's earlier, inconsistent statements to the Patent Office. Rather, both Courts applied a *per se* rule, improperly grafted from the Federal Circuit's claim construction jurisprudence, to conclude that the statements were irrelevant as a matter of law. Thus, the issue presented is purely one of law: Did the Federal Circuit and the District Court err in failing to apply the statute and regulations governing disclosure in the context of a patent term extension?

Both the District Court and the Federal Circuit dutifully cited the controlling Patent Office regulation, which requires an applicant for patent term extension to

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[1] Hereinafter cited as "Opp. ___."

disclose "material information."[2] 37 C.F.R. § 1.765(a); App. 12, 41. However, neither Court conducted the materiality analysis mandated by the regulation, as evidenced by the complete lack of any analysis by either Court of whether Pfizer's earlier representations regarding the '893 patent were material under the proper standard.

Instead, in construing the claims of the '893 patent, the District Court refused to consider: (1) Pfizer's earlier, inconsistent representations that the '893 patent does not disclose, teach, or enable enantiomers, (2) the Board's decision adopting Pfizer's representations, and (3) the existence of the later '995 patent, specifically disclosing and claiming enantiomers. App. 31. The District Court premised its refusal on Federal Circuit precedent, which the District Court interpreted as barring consideration of such information. *Id.* Based on its interpretation of that precedent, the District Court characterized this information as "irrelevant" in the context of claim construction. App. 43.

Based solely on its conclusion that this information could not be considered for purposes of *claim construction*, the District Court erroneously concluded this information was necessarily not material, and therefore not subject to the patent term extension disclosure requirements of 37 C.F.R. § 1.765(a). *Id.* Remarkably, the District Court reached this conclusion even though it conceded that

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[2] Pfizer's characterization of the regulation governing disclosure in a patent term extension proceeding as a "well-established standard" is ill-founded. Opp. 5. Ranbaxy is unaware of any prior Federal Circuit case addressing the standard of disclosure in a patent term extension proceeding or addressing invalidity of patent term extension under 35 U.S.C. § 282, ¶ 4, for failure to comply with the disclosure requirement.

"there may be a degree of tension between the positions taken by Pfizer in each instance." App. 32. That "tension" renders Pfizer's earlier statements *at least* material under the regulations governing disclosure in a patent term extension proceeding; it is of no moment that these statements may not be available for purposes of the separate and distinct claim construction inquiry. Indeed, as even Pfizer concedes, "[t]he regulations [governing disclosure in a patent term extension proceeding] have nothing to do with claim construction." Opp. 15.

Contrary to Pfizer's assertion in its Brief in Opposition, the District Court never conducted the fact-based analysis of whether the information that Pfizer withheld from the Patent Office was material under the proper standard. Instead, the District Court deemed the information *per se* irrelevant *as a matter of law* based on inapplicable precedent governing a completely different inquiry – claim construction. The District Court committed legal error in failing to apply the statutorily-mandated standard of disclosure governing patent term extension proceedings and in failing to assess materiality under this standard.

Pfizer's Opposition disingenuously suggests that the District Court actually analyzed the materiality of the information that Pfizer withheld during the patent term extension proceedings. Opp. 3-4, 10. Review of the District Court's opinion shows it conducted no such analysis. App. 31-32, 40-43.

In the District Court, Ranbaxy asserted that judicial estoppel should preclude Pfizer from taking a litigation position regarding the '893 patent inconsistent with its representations to the Patent Office Board. In addressing judicial estoppel, not the validity of the patent term

extension, the District Court found that Pfizer's litigation position was not "irreconcilably inconsistent" with its prior representations to the Patent Office regarding the scope of the '893 patent. App. 32. This was the only context in which the District Court opined regarding the substance of Pfizer's earlier representations to the Patent Office. This judicial estoppel analysis involved a wholly-different – and higher – standard than the "materiality" standard applicable in the patent term extension context. Moreover, the District Court's judicial estoppel analysis was wholly separate from its analysis of the patent term extension. *Compare* App. 31-32 (assessing judicial estoppel) *to* App. 43 (assessing invalidity of the patent term extension). Indeed, in analyzing the patent term extension, the District Court did not even refer to, or rely upon, its analysis of Pfizer's representations in the context of judicial estoppel. App. 43.

As noted above, the District Court recognized that there was "a degree of tension" between Pfizer's litigation position and its earlier representations to the Patent Office. App. 32; *see Graham v. John Deere Co.*, 383 U.S. 1, 32 (1966) (rejecting a patentee's litigation position in support of validity, in part due to "a substantial divergence in respondent's present position" from that urged before the Patent Office). This "tension" was manifest in Pfizer's assertion in the litigation that the '893 patent covered atorvastatin calcium, and its previous representation to the Patent Office that the '893 patent does not disclose, teach, or enable that compound. This "tension" confirms that under the proper standard, Pfizer's representations were material in the patent term extension proceeding. Contrary to Pfizer's contention, the District Court's determination that Pfizer's positions were not "irreconcilably

inconsistent" for purposes of judicial estoppel does not mean that the statements were irrelevant, and therefore immaterial, to the patent term extension proceedings as a matter of law.

In two cursory sentences, the Federal Circuit upheld the District Court's determination that the information Pfizer withheld from the Patent Office was not material because it was "irrelevant." App. 12. The Federal Circuit concluded that the District Court's "factual finding" regarding materiality "was not clearly erroneous." *Id.* However, the District Court had made no such finding. Rather, the District Court never analyzed whether Pfizer's representations were material under the proper standard; it merely deemed Pfizer's representations irrelevant as a matter of law. Thus, the Federal Circuit purported to affirm a factual finding, but necessarily adopted and affirmed the District Court's application of a *per se* legal rule. At the very least, clarification of the Federal Circuit's reasoning is required. *Cf. Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811 (1986) (granting certiorari, vacating the decision below, and remanding the case for further consideration under the proper standard "[i]n the absence of an opinion clearly setting forth the views of the Court of Appeals. . . .").

Neither the District Court nor the Federal Circuit applied the standard of materiality duly promulgated by the Patent Office in 37 C.F.R. § 1.765(a). Instead, both Courts supplanted this standard in favor of a *per se* rule that representations made to the Patent Office during prosecution of a formally unrelated patent application are irrelevant. Review is necessary to correct this error of law.

II. THE ISSUE PRESENTED IS NOT ACADEMIC AND IS LIKELY TO EVADE REVIEW IF NOT ADDRESSED AT THIS TIME

In its Opposition, Pfizer contends that the issue presented is academic and could not affect the outcome in this case. Opp. 12-13. Pfizer is wrong.

Under 35 U.S.C. § 282, ¶ 4, a patent term extension is invalid if an applicant failed to comply with its duty of disclosure mandated by the Patent Office in 37 C.F.R. § 1.765(a). The question presented directly addresses whether the District Court and the Federal Circuit applied the proper standard in determining whether Pfizer complied with its disclosure obligations under the controlling regulation. If Pfizer did not fulfill its disclosure obligations, the '893 patent term extension is invalid.[3] 35 U.S.C. § 282, ¶ 4; 35 U.S.C. § 156(d)(4); 37 C.F.R. § 1.765(a). Invalidity of the '893 patent term extension removes the sole legal impediment to Ranbaxy immediately marketing its generic version of Lipitor®. Thus, the question

[3] Pfizer repeatedly attempts to recast the issue as whether there was "inequitable conduct" during prosecution of the patent term extension, Opp. i, 5, 8, 12, 13. However, the relevant statutory provision does not address inequitable conduct, but rather "[i]nvalidity" for failure to comply with the controlling regulations. 35 U.S.C. § 282, ¶ 4. Pfizer uses the incorrect term "inequitable conduct" in an effort to import a further requirement of "intent to deceive" into the inquiry and allege that Ranbaxy cannot meet this requirement. Opp. 6, 13. Contrary to Pfizer's assertion, intent to deceive is irrelevant to whether the patent term extension is invalid. Rather, the controlling regulation, 37 C.F.R. § 1.765(c), requires only a showing of "gross negligence." Ranbaxy easily satisfied this standard as it is undisputed that the attorney who prosecuted the patent term extension application was fully aware of the information that Pfizer withheld from the Patent Office during the patent term extension proceedings.

presented is in no way academic to the dispute between the parties.

Pfizer contends that because the Courts have determined that the withheld information is irrelevant to claim construction, the information is immaterial to the patent term extension proceedings and cannot affect the outcome in this case. Opp. 12-13. This contention incorrectly applies the same *per se* rule as did the District Court and the Federal Circuit. The inquiries for claim construction and materiality are distinct and involve different standards. Neither controls the other. As Pfizer readily admits, the patent term extension "regulations have nothing to do with claim construction." *Id.* at 15. Accordingly, the question presented is not academic.

The question presented has great importance in this case because it determines when generic Lipitor® will become available in the United States. *See* Pet. 2-3, 29-30. The question also has far-reaching implications. First, if not addressed at this time, the issue will likely evade review. *Id.* at 27-28. Second, the issue is of national importance as it directly impacts the length of patent protection for prescription drugs, when generic alternatives will become available, and how forthcoming pharmaceutical companies will be in the future in disclosing information to the Patent Office when seeking lucrative patent term extensions. *Id.* at 28-29.

The *per se* rule applied by the District Court and now endorsed by the Federal Circuit is an affront to the Patent Office's authority and undermines the disclosure obligations duly promulgated by the Patent Office. Moreover, the new *per se* rule deprives the Patent Office of the information it demands under 37 C.F.R. § 1.765(a) to properly

assess patent term extension applications. As shown by the facts of this particular case, the Patent Office has been denied any opportunity to determine whether Pfizer's earlier, inconsistent representations, as well as the decision of the Patent Office Board adopting those representations, were material to the patent term extension proceedings, despite being the agency charged with making this determination in the first instance. By creating a *per se* rule that allows a patent term extension applicant to withhold information from the Patent Office with impunity, the District Court and the Federal Circuit have instituted a new legal rule that contravenes the controlling Patent Office regulation and can only lead to abuse of the patent system. *Id.* at 28-29.

III. THE PATENT OFFICE'S VIEW OF ITS OWN REGULATION SHOULD BE SOLICITED

The Patent Office promulgated the regulation, 37 C.F.R. § 1.765(a), which controls the disclosures required in a patent term extension proceeding. As the agency charged with evaluating patent term extension applications in view of the information disclosed by applicants under this regulation, the Patent Office is uniquely qualified to assess whether the information that Pfizer withheld is material. Here, Pfizer denied the Patent Office the opportunity to assess the withheld information in the first instance. There is no reason to now deny the Patent Office the opportunity to address the new, *per se* rule adopted by the District Court and endorsed by the Federal Circuit. The Patent Office is also uniquely qualified to explain the ramifications of this *per se* rule, and to address how such a rule would undermine the Patent Office's evaluation of future patent term extension applications.

Given the Patent Office's unique position and qualification to address these issues, Ranbaxy urges that the views of the government, especially those of the Patent Office, be solicited in determining whether to grant the Petition for Writ of Certiorari in this case.

CONCLUSION

For the reasons stated and those previously presented, the Petition for Writ of Certiorari should be granted.

Respectfully submitted,

WILLIAM R. ZIMMERMAN
Counsel of Record
DARRELL L. OLSON
JOSEPH M. REISMAN
PAYSON LEMEILLEUR
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, California 92614
(949) 760-0404

Attorneys for Petitioners